FEB - 1 2012 K112736

# 510(K) SUMMARY

## 1. GENERAL INFORMATION

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|---|---|
| Trade Name | LigaPASS |
| Classification Name | Bone Fixation Cerclag |
| Class | Class II |
| Product Code | JDQ |
| CFR section | 888.3010 |
| Device panel | Orthopedic |
| Legally marketed predicate devices | Universal Clamp System (Abbott Spine)=K060009 |
| Reason for Special 510(k) | Additional components |
| Submitter | MEDICREA International<br>14 Porte du Grand Lyon<br>01700 Neyron, France |
| Contact | J.D. Webb<br>1001 Oakwood Blvd<br>Round Rock, TX 78681<br>512-388-0199<br>E-Mail: ortho.medix@sbcglobal.net |

## 2. PREDICATE DEVICE DESCRIPTION

The Universal Clamp System is a temporary orthopedic implant intended to provide stabilization during the development of solid bony fusion and aid in the repair of bone fractures. The device system is designed to be incorporated into constructs and used in conjunction with other medical implants.

The indications for use include, but are not limited to, the following applications: Spinal trauma surgery, used in sublaminar, interspinous or facet wiring techniques; Spinal reconstructive surgery, incorporated into constructs for the purpose of spinal deformities such as scoliosis, kyphosis, spondylolisthesis, etc; spinal degenerative surgery, as an adjunct to spinal fusions.

The Universal Clamp System may also be used with other medical implants made of stainless steel whenever "wiring" may help secure the attachment of other implants.

## 3. DEVICE DESCRIPTION

The LigaPASS connector connects a rod to a vertebra. This connector can independently tighten the rod and the bone anchor. The LigaPASS connector is composed by a connector body, a rod set screw, a locking set screw for the band and a polyester band.

## 4. INTENDED USE

The LigaPASS is a temporary implant for use in orthopedic surgery on skeletally mature patients. The system is intended to provide temporary stabilization as a bone anchor during the development of solid bony fusion and aid in the repair of bone fractures. The indications for use include the following applications:

Spinal trauma surgery, used in sublaminar, interspinous, or facet wiring techniques;
Spinal reconstructive surgery, incorporated into constructs for the purpose of correction of spinal deformities such as scoliosis, kyphosis, spondylolisthesis;
Spinal degenerative surgery, as an adjunct to spinal fusions;

The LigaPASS may also be used in conjunction with other medical implants made of titanium or chrome cobalt alloy whenever "wiring" may help secure the attachment of other implants.

**SUBSTANTIAL EQUIVALENCE CLAIMED TO PREDICATE DEVICES**

The LigaPASS is similar to Universal Clamp System, as they have the same intended use, and substantially similar indications for use, technological characteristics and principles of operation.

**NON-CLINICAL TEST SUMMARY**

The following tests were conducted according to ASTM F1717 *"Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model"* and ASTM F1798 *"Standard Guide for Evaluating the Static and Fatigue Properties of Interconnection Mechanisms and Subassemblies Used in Spinal Arthrodesis Implants"*:

1. Static testing in a load to failure mode in torsion
2. Static testing in a load to failure mode in compression bending
3. Dynamic compression bending testing
4. Static testing in a load to failure mode in tension
5. Dynamic tension testing

The results of these tests indicate that the LigaPASS is equivalent to predicate devices.

**CLINICAL TEST SUMMARY**

No clinical studies were performed.

**CONCLUSIONS: NON-CLINICAL AND CLINICAL**

The LigaPASS is substantially equivalent to the predicate devices in terms of indications for use, design, material, and function.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Medicrea International
% The Orthomedix Group
Mr. J.D. Webb
1001 Oak Wood Boulevard
Round Rock, Texas 78681

FEB - 1 2012

Re: K112736
Trade/Device Name: LigaPASS
Regulation Number: 21 CFR 888.3010
Regulation Name: Bone fixation cerclage
Regulatory Class: Class II
Product Code: JDQ
Dated: December 11, 2011
Received: December 29, 2011

Dear Mr. Webb:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

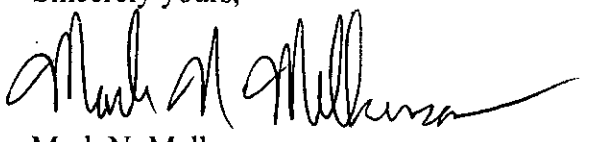
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to: http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address: http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

## STATEMENT OF Indications for Use

**510(k) Number (if known):** K112736
**Device Name**: LigaPASS

**LigaPASS**
**Indications for Use**

The LigaPASS is a temporary implant for use in orthopedic surgery on skeletally mature patients. The system is intended to provide temporary stabilization as a bone anchor during the development of solid bony fusion and aid in the repair of bone fractures. The indications for use include the following applications:

- Spinal trauma surgery, used in sublaminar, interspinous, or facet wiring techniques;
- Spinal reconstructive surgery, incorporated into constructs for the purpose of correction of spinal deformities such as scoliosis, kyphosis, spondylolisthesis;
- Spinal degenerative surgery, as an adjunct to spinal fusions;

The LigaPASS may also be used in conjunction with other medical implants made of titanium or cobalt chrome alloy whenever "wiring" may help secure the attachment of other implants.

| | | |
|---|---|---|
| Prescription Use ✓<br>(Part 21 CFR 801 Subpart D) | AND/OR | Over-The-Counter Use _____<br>(21 CFR 801 Subpart C) |

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K112736